federal register

TUESDAY, AUGUST 6, 1974

WASHINGTON, D.C.

Volume 39 ■ Number 152

PART II

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

■

ANTIBIOTIC, NITROFURAN, AND SULFONAMIDE DRUGS IN ANIMAL FEED

Proposed Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Parts 121, 135e, 135g, 144]

ANTIBIOTIC, NITROFURAN, AND SULFONAMIDE DRUGS IN THE FEED OF ANIMALS

Proposed Deletion of Regulations Regarding Use

Section 135.109 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (21 CFR 135.109) requires the submission by specified dates of new animal drug applications (NADAs) and specified commitments and information as a basis for continued marketing of antibacterial drugs intended for use at subtherapeutic levels in animal feed. Elsewhere in this issue of the FEDERAL REGISTER the Commissioner of Food and Drugs proposes to amend § 135.109 by listing therein the antibacterial drugs for which satisfactory responses to § 135.109 have been received, along with the sponsors and conditions of use of such drugs.

As a corollary to that proposed amendment to § 135.109, the Commissioner proposes to amend 21 CFR Parts 121, 135e, 135g, and 144 as set forth below to revoke those antibacterial drugs intended for use in animal feed which are not in compliance with the requirements of § 135.109. Included in this proposal is the revocation of § 135e.1000 *Combination antibiotic drugs in animal feeds no longer sanctioned* since the provisions of that section are otherwise encompassed by this proposal.

Certain uses of oxytetracycline and neomycin, alone or in combination with other drugs, the uses of which are not the subject of published regulations or for which commitments have not been received and for which usages are not listed in the corresponding document published elsewhere in this issue of the FEDERAL REGISTER, are subject to the proposed revocation. Uses of oxytetracycline and neomycin alone or in combination with other drugs are permitted on an interim basis in accordance with the conditions set forth in the corresponding amendments to § 135.109.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351; (21 U.S.C. 360b, 371(a))) and under authority delegated to the Commissioner (21 CFR 2.120), it is proposed that Chapter I of Title 21, Code of Federal Regulations be amended as follows:

PART 121—FOOD ADDITIVES

1. In § 121.207(c) by revising the table to read as follows:

§ 121.207 Zoalene.

* * * * *

(c) * * *

Zoalene in complete feeds for chickens and turkeys

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Zoalene	113.5–170.3 (0.0125%–0.01875%)			For turkeys grown for meat purposes only	Prevention and control of coccidiosis.
1.2 Zoalene	113.5–170.3 (0.0125%–0.01875%)	Carbarsone (not U.S.P.).	227–340.5 (0.025%–0.0375%)	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; aid in the prevention of blackhead.
a. Zoalene	113.5–170.3	Arsanilic acid	90 (0.01%)	For turkeys grown for meat purposes only; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency, improving pigmentation.
b. Zoalene	113.5–170.3	Sodium arsanilate	90 (0.01%)	For turkeys grown for meat purposes only; withdraw 5 days before slaughter.	Do.
c. Zoalene	113.5–170.3	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4	§ 121.262, table 1, item 2.1.	§ 121.262, table 1, item 2.1.
2.1 Zoalene	113.5 (0.0125%)			For broiler chickens	Prevention and control of coccidiosis.
2.2 Zoalene	113.5 (0.0125%)	Arsanilic acid	90 (0.01%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.3 Zoalene	113.5 (0.0125%)	Sodium arsanilate	90 (0.01%)	do	Do.
2.4 Zoalene	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	do	Prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.5 Zoalene	113.5 (0.0125%)	Lincomycin	2	For floor raised broiler chickens; do not feed to laying chickens; to be fed as the sole ration; as lincomycin hydrocloride, monohydrate provided by sponsor No. 037, see § 135.501(c) of this chapter; zoalene provided by sponsor No. 012, see § 135.501(c) of this chapter.	Increase in rate of weight gain, improved feed efficiency, and as an aid in the prevention and control of coccidiosis.
a. 2.1, 2.2, or 2.4	113.5	Penicillin	2.4–50	For broiler chickens; as procaine penicillin	Growth promotion and feed efficiency.
b. 2.1, or 2.4	113.5	Bacitracin	4–50	For broiler chickens; as bacitracin methylene disalicylate, or zinc bacitracin.	Do.
3.1 Zoalene	36.3–113.5 (0.004%–0.0125%)			For replacement chickens; in complete feed only; (grower ration not to be fed to birds over 14 weeks of age), as follows:	Development of active immunity to coccidiosis.

Growing conditions	Amount of zoalene in feed for birds by age group: Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0085%)

3.2 Zoalene	36.3–113.5 (0.004%–0.0125%)	Arsanilic acid	90 (0.01%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic, as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
				Growing conditions	Starter ration / Grower ration
				Severe exposure	*Grams per ton*: 113.5 (0.0125%) / 75.4–113.5 (0.0083%–0.0125%)
				Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%) / 36.3–75.4 (0.004%–0.0085%)
3.3 Zoalene	36.3–113.5 (0.004%–0.0125%)	Sodium arsanilate	90 (0.01%)	For replacement chickens; etc.—Continued	Development of active immunity to coccidiosis etc.—Continued
3.4 Zoalene	36.3–113.5 (0.004%–0.0125%)	3-Nitro-4-hydroxy-phenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	do	Do.

* * * * * * *

2. In § 121.208(d) by revising tables 1 and 2 to read as follows:

§ 121.208 Chlortetracycline.

* * * * * * *

(d) * * *

TABLE 1.—*Chlortetracycline in complete chicken and turkey feeds*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Chlortetracycline	50–100			For chickens and turkeys; as chlortetracycline hydrochloride.	During times of stress, for prevention of diseases named in this section caused by organisms susceptible to the indicated levels of the chlortetracycline salt.
2. Chlortetracycline	50–100			For chickens; as chlortetracycline hydrochloride.	Prevention of chronic respiratory disease (air-sac infection).
3. Chlortetracycline	50–100			For turkeys; as chlortetracycline hydrochloride.	Prevention of infectious sinusitis, hexamitiasis.
4. Chlortetracycline	50–100			For laying chickens; as chlortetracycline hydrochloride.	Maintaining or increasing egg production or hatchability of eggs.
5. Chlortetracycline	50–100			For chicks; as chlortetracycline hydrochloride	Prevention of early mortality due to organisms susceptible to chlortetracycline.
6. Chlortetracycline	100–200			For chickens; not to be fed to laying chickens; as chlortetracycline hydrochloride.	Treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.
7. Chlortetracycline	100–200			For turkeys; as chlortetracycline hydrochloride	Treatment of blue comb (nonspecific infectious enteritis, mud fever), infectious sinusitis, hexamitiasis; prevention of synovitis.
8. Chlortetracycline	100–200			For chickens; not be fed to laying chickens; as chlortetracycline hydrochloride, as follows: In low-calcium feed containing 0.8 percent dietary calcium, not to be fed continuously for more more than 8 weeks; in low-calcium feed containing 0.40 percent to 0.55 percent dietary calcium, not to be fed continuously for more than 5 days; in low-calcium feed containing 0.8 percent dietary calcium and 1 percent to 1.5 percent sodium sulfate, to be fed continuously for not more than the first 3 weeks of life.	Treatment of chronic respiratory disease (air-sac infection), blue comb (nonspecific infectious enteritis); prevention of synovitis.
9. Chlortetracycline	200			For chickens; not to be fed to laying chickens; as chlortetracycline hydrochloride, as follows: In low-calcium feed containing 0.8 percent dietary calcium, not to be fed continuously for more than 8 weeks; in low-calcium feed containing 0.8 percent dietary calcium and 1.0 percent to 1.5 percent sodium sulfate, to be fed continuously for not more than the first 3 weeks of life.	Prevention and control of coccidiosis caused by *E. necatrix* and *E. tenella*.
10. Chlortetracycline	200			For chickens; not to be fed to laying chickens; as chlortetracycline hydrochloride; in low-calcium feed containing 0.4% to 0.55% dietary calcium, not to be fed continuously for more than 5 days.	Treatment of coccidiosis caused by *E. necatrix* and *E tenella*.
11. Chlortetracycline	200			For chickens; not to be fed to laying chickens; as chlortetracycline hydrochloride.	Control of synovitis.
12. Chlortetracycline	200			For turkeys; as chlortetracycline hydrochloride	Do.
13. Chlortetracycline	400			For turkey poults not over 4 weeks of age; in low calcium feed containing 1 percent total calcium with not less than 0.45 percent calcium from calcium sulfate; as chlortetracycline hydrochloride.	Aid in reducing mortality due to paratyphoid caused by *Salmonella typhimurium*.
14. Chlortetracycline	500			For chickens; not to be fed to laying chickens; as chlortetracycline hydrochloride; in feed containing 0.8 percent dietary calcium; not to be fed continuously for more than 5 days; withdraw 24 hours prior to slaughter.	Aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.
15. Chlortetracycline	200			For broiler chickens; in low calcium feed containing 0.8 percent dietary calcium and 1.5 percent sodium sulfate; feed continuously as sole ration for not more than the first 3 weeks of life.	Treatment of chronic respiratory disease caused by strains of *Mycoplasma gallisepticum* susceptible to chloretetracycline.

TABLE 2.—*Chlortetracycline in complete swine feed*

Principal ingredient	Quantity	Combined with—	Quantity	Limitations	Indications for use
	Grams per ton		*Grams per ton*		
1. Chlortetracycline [1]	50–100			As chlortetracycline hydrochloride	Maintenance of weight gain in the presence of atrophic rhinitis; reduction of the incidence of cervical abscesses; prevention of bacterial swine enteritis; prevention of bacterial swine enteritis during times of stress.
2. Chlortetracycline [1]	100–200			As chlortetracycline hydrochloride	Treatment of bacterial swine enteritis.
3. Chlortetracycline	200			Sole medication; as chlortetracycline hydrochloride.	As an aid in reducing spread of leptospirosis.
4. Chlortetracycline	400			To be fed for 14 days as sole medication; as chlortetracycline hydrochloride.	As an aid in reducing shedding of leptospirae; as an aid in reducing the abortion rate of swine and the mortality rate of newborn pigs when leptospirosis is present.

[1] See also § 121.200(c)(1).

* * * * * * * * *

3. In § 121.210(c) by revising the table to read as follows:

§ 121.210 Amprolium.

* * * * * * * * *

(c) * * *

Amprolium in complete chicken and turkey feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Amprolium	113.5–227 (0.0125%–0.025%)			For turkeys	Prevention of coccidiosis.
a. 1.1	113.5–227	Penicillin	2.4–50	For turkeys; as procaine penicillin	Growth promotion and feed efficiency.
b. 1.1	113.5–227	Bacitracin	4–50	For turkeys; as bacitracin methylene disalicylate.	Do.
c. 1.1	113.5–227	Arsanilic acid	90 (0.01%)	For turkeys; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
d. 1.1	113.5–227	Sodium arsanilate	90 (0.01%)	For turkeys; withdraw 5 days before slaughter	Do.
e. 1.1	113.5–227	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4	§ 121.262, table 1, item 2.1	§ 121.262, table 1, item 2.1.
2.1 Amprolium	113.5–227 (0.0125%–0.025%)			For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired.	Prevention of coccidiosis.
2.2 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate	3.6 (0.0004%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; not for laying hens.	Do.
2.3 Amprolium	113.5–227 (0.0125%–0.025%)	Arsanilic acid	90 (0.01%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter.	Prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.4 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate + Arsanilic acid	3.6 (0.0004%) 90 (0.01%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter; not for laying hens.	Do.
2.8 Amprolium	113.5–227 (0.0125%–0.025%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter.	Prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
2.9 Amprolium	113.5–227 (0.0125%–0.025%)	Ethopabate + 3-Nitro-4-hydroxyphenylarsonic acid.	3.6 (0.0004%) 22.7–45.4 (0.0025%–0.005%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; as sole source of organic arsenic; withdraw 5 days before slaughter; not for laying hens.	Do.
2.10 Amprolium	113.5 (0.0125%)	Ethopabate + 3-Nitro-4-hydroxyphenylarsonic acid. + Lincomycin	3.6 (0.0004%) 45.4 (0.005%) 2–4	For floor-raised broiler chickens; not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 days before slaughter; as sole source of amprolium and organic arsenic.	For increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis in floor-raised broiler chickens.
2.11 Amprolium	113.5 (0.0125%)	Ethopabate + Lincomycin	3.6 (0.0004%) 2–4	For floor-raised broiler chickens; not for laying chickens; as lincomycin hydrochloride monohydrate; as sole source of amprolium.	Do.
a. 2.1 or 2.2	113.5–227	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b. 2.1, 2.2, or 2.9	113.5–227	Bacitracin	4–50	As bacitracin methylene disalicylate	Do.
c. 2.1	113 5–227	Sodium arsanilate	90 (0.01%)	§ 121.254(c), item 1	Growth promotion and feed efficiency; improving pigmentation.
3.1 Amprolium	36.3–113.5 (0.004%–0.0125%)			For replacement chickens; as follows:	Development of active immunity to coccidiosis.

Growing conditions	Amount of amprolium in feed for birds, by age groups: Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Grams per ton	*Grams per ton*	*Grams per ton*
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

3.2 Amprolium	36.3–113.5 (0.004%–0.0125%)	Arsanilic acid	90 (0.01%)	For replacement chickens; as specified in item 3.1 of this table; withdraw 5 days before slaughter; as sole source of organic arsenic.	Development of active immunity to coccidiosis, growth promotion and feed efficiency; improving pigmentation.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
3.3 Amprolium	36.3–113.5 (0.004%–0.0125%)	Sodium arsanilate	90 (0.01%)	For replacement chickens; as specified in item 3.1 of this table; withdraw 5 days before slaughter; as sole source of organic arsenic.	Do.
a. 3.1 or 3.2	36.3–113.5	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b. 3.1	36.3–113.5	3-Nitro-4-hydroxyphepylarsoni acid.	22.7–45.4	§ 121.262, table I, item 1.1	§ 121.262, table I, item 1.1.
4.1 Amprolium	72.6–113.5 (0.008%–0.0125%)			For broiler chickens	Prevention of coccidiosis caused by *E. tenella* only.
4.2 Amprolium	72.6–113.5 (0.008%–0.0125%)	Arsanilic acid	90 (0.01%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention of coccidiosis caused by *E. tenella* only; growth promotion and feed efficiency; improving pigmentation.
4.3 Amprolium	72.6–113.5 (0.008%–0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	do	Do.
a. 4.1	72.6–113.5	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b. 4.1	72.6–113.5	Sodium arsanilate	90	Withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
5.1 Amprolium	113.5 (0.0125%)			For moderate outbreaks of coccidiosis in laying chickens; administer for 2 weeks.	Treatment of coccidiosis.
6.1 Amprolium	227 (0.025%)			For severe outbreaks of coccidiosis in laying chickens; administer for 2 weeks.	Do.
7.1 Amprolium	113.5 (0.0125%)	Ethopabate	36.3 (0.004%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; not for chickens over 16 weeks of age.	As an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur.
a. 7.1		Bacitracin	4	For broiler chickens; do not feed to laying chickens; as sole source of amprolium; not for use as a treatment for outbreaks of coccidiosis; as bacitracin methylene disalicylate as provided by Code No. 028 in § 135.501(c) of this chapter; feed as the sole ration from the time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; approval for this combination granted to firm No. 023 as identified in § 135.501(c) of this chapter.	To aid in prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, *E. brunetti* is likely to occur; for increased rate of weight gain in broiler chickens raised in floor pens.
b. 7.1		3-Nitro-4-hydroxyphenylarsonic acid.	45.4 (0.005%)	For broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; 3-nitro-4-hydroxyphenylarsonic acid as provided by code No. 031 in § 135.501(c) of this chapter; approval for this combination granted to firm No. 023 as identified in § 135.501(c) of this chapter.	Do.
8.1 Amprolium	113.5 (0.0125%)			For laying chickens	Prevention of coccidiosis.
9.1 Amprolium	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid. + Ethopabate + Bacitracin methylene disalicylate.	34 (0.00375%) 36.3 (0.004%) 5–35	For floor-raised broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of amprolium and organic arsenic; do not use as a treatment for outbreaks of coccidiosis; feed as the sole ration from time chickens are placed on litter until past the time when coccidiosis is ordinarily a hazard; amprolium and ethopabate as provided by code No. 023 in § 135.501(c) of this chapter; bacitracin methylene disalicylate as provided by code No. 028 in § 135.501(c) of this chapter; 3-nitro-4-hydroxyphenylarsonic acid as provided by code No. 031 in § 135.501(c) of this chapter; approval for this combination granted to firm No. 023 as identified in § 135.501(c) of this chapter.	For increased rate of weight gain and as an aid in the prevention of coccidiosis where severe exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.
10.1 Amprolium	113.5 (0.0125%)	3-Nitro-4-hydroxyphenylarsonic acid. + Ethopabate + Bacitracin methylene disalicylate.	34 (0.00375%) 36.3 (0.004%) 20–35	do	For increased rate of weight gain, improved feed efficiency, and as an aid in the prevention of coccidiosis where servere exposure to coccidiosis from *E. acervulina*, *E. maxima*, and *E. brunetti* is likely to occur in broiler chickens raised in floor pens.

* * * * * * * *

4. In § 121.213(d) by deleting tables 1 and 2 and adding a new table to read as follows:

§ 121.213 Hygromycin B.

* * * * * * * *

(d) * * *

Hygromycin B in complete chicken and swine feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Hygromycin B	8–12				Control of infestation of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*) and capillary worms (*Capillaria obsignata*).
2. Hygromycin B	12			For swine; withdraw 48 hours prior to slaughter.	Control of infestation of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*).

* * * * * * * *

5. In § 121.220(d) by revising the table to read as follows:

§ 121.220 Nystatin.

* * * * * * * *

(d) * * *

Nystatin in chicken and turkey feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Nystatin	100			For growing chickens; to be fed for 7 to 10 days	Treatment of crop mycosis and mycotic diarrhea (*Candida al bicans*).
2. Nystatin	100			For laying chickens; to be fed for 7 to 10 days	Do.
3. Nystatin	100			For growing turkeys; to be fed for 7 to 10 days	Do.

* * * * * * *

6. By revising § 121.225 to read as follows:

§ 121.225 Antibiotics for growth promotion and feed efficiency.

The antibiotics listed in this section may be safely used in animal feeds as an aid in stimulating growth and improving feed efficiency, in accordance with the following prescribed conditions:

(a) *Procaine penicillin.* Procaine penicillin as follows:

(1) Procaine penicillin is the procaine salt of the antibiotic substance produced by the growth of Penicillium notatum or Penicillium chrysogenum or the same antibiotic substances produced by any other means.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens, turkeys, and pheasants in an amount not less than 2.4 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of quail not over 5 weeks of age, in an amount not less than 5 grams nor more than 20 grams per ton of finished feed.

(iii) With streptomycin in the feed of chickens and turkeys at a level of 2.4 to 7.5 grams per ton of procaine penicillin with 12.0 to 37.5 grams per ton of streptomycin and in the feed of chickens at a level of 3.75 to 7.5 grams per ton of procaine penicillin and 18.75 to 37.5 grams per ton of streptomycin.

(iv) With streptomycin in the feed of swine at a level of 1.5 to 7.5 grams per ton of procaine penicillin combined with 7.5 to 37.5 grams per ton of streptomycin in the finished feed.

(b) Zinc bacitracin. Zinc bacitracin as follows:

(1) Zinc bacitracin is the zinc salt growth of Bacillus subtilis var. Tracy or the same antibiotic substance produced by any other means, and for the purposes of this paragraph refers to zinc bacitracin or feed grade zinc bacitracin.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equivalent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys in an amount not less than 4 grams nor more than 50 grams per ton of finished feed.

(ii) In feed for growing cattle, in an amount providing not less than 35 milligrams nor more than 70 milligrams per animal per day.

(iii) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(c) *Bacitracin methylene disalicylate.* Bacitracin methylene disalicylate as follows:

(1) Bacitracin methylene disalicylate is the methylene disalicylate salt of the antibiotic substance produced by growth of Bacillus subtilis var. Tracy or the same antibiotic substance produced by any other means, and for the purpose of this paragraph refers to bacitracin methylene disalicylate or feed grade bacitracin methylene disalicylate.

(2) The quantities of the antibiotics referred to in this paragraph refer to activities equilavent to those of the appropriate antibiotic master standards.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys in an amount not less than 4 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(d) *Chlortetracycline.* Chlortetracycline as follows:

(1) Chlortetracycline is the antibiotic substance produced by growth of Streptomyces aureofaciens or the same antibiotic substance produced by any other means, and for the purposes of this paragraph refers to chlortetracycline or feed grade chlortetracycline.

(2) The quantities of the antibiotic referred to in this paragraph refer to activity equivalent to that of the appropriate antibiotic master standard.

(3) It is used or intended for use:

(i) In the feed of chickens and turkeys, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(ii) In the feed of mink, in an amount not less than 20 grams nor more than 50 grams per ton of finished feed, and also as an aid in increasing pelt size.

(iii) In the feed of horses up to 1 year of age in the amount of 85 milligrams per head per day, where such horses are not to be slaughtered for food purposes.

(iv) In the feed of swine, in an amount not less than 10 grams nor more than 50 grams per ton of finished feed.

(v) In the feed of calves, in an amount not less than 25 milligrams per head per day nor more than 70 milligrams per head per day in finished feed.

(vi) In the feed of growing cattle, in an amount equal to 70 milligrams per head per day in finished feed.

(vii) In the feed of calves up to 250 pounds in weight in an amount providing 0.1 milligram per pound of body weight per day in milk replacers or starter feeds.

(e) *Erythromycin thiocyanate.* Erythromycin thiocyanate as follows:

(1) Erythromycin thiocyanate is the thiocyanate salt of the antibiotic substance produced by the growth of Streptomyces erythreus or the same antibiotic substance produced by any other means.

(2) The levels of antibiotics listed are expressed in terms of the weight of erythromycin master standard. One gram of erythromycin thiocyanate is equivalent to 0.925 gram of erythromycin master standard.

(3) It is used or intended for use:

(i) In the feed of chickens, in an amount not less than 4.6 grams nor more than 18.5 grams per ton of finished feed.

(ii) In the feed of turkeys not over 12 weeks of age, in an amount not less than 9.25 nor more than 18.5 grams per ton of finished feed.

(f)–(v) [Reserved]

(w) *Labeling requirements.* (1) To assure safe use, the label and labeling of the additive, any combination of additives, and any feed additive supplement, feed additive concentrate, or feed additive premix prepared therefrom, shall bear, in addition to the other information required by the act, the following:

(i) The name of the additive or additives.

(ii) A statement of the quantity of each contained in any mixtures.

(iii) A statement of the conditions for which the feed is to be used.

(iv) Adequate mixing directions to provide a complete feed with the proper concentration of the additive or additives, whether or not intermediate feed additive supplements, feed additive concentrates, or feed additive premixes are also used.

NOTE.—§ 121.225(w) was amended by an order published in the FEDERAL REGISTER on March 20, 1965, 30 FR 3708, effective January 1, 1966, and was stayed at 30 FR 12353, September 28, 1965.

§ 121.232 [Reserved]

7. By revoking § 121.232 *Bacitracin* and reserving it for future use.

8. In § 121.233 by revising tables 1 and 2 to read as follows:

§ 121.233 Bacitracin.

* * * * *

(d) * * *

TABLE 1.—*Zinc bacitracin in complete chicken and turkey feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Bacitracin	10–50			For chickens; 50 gm. per ton first 4 to 6 weeks of egg production; 10–50 gm. per ton for remainder of egg-laying period; as zinc bacitracin.	Maintaining or increasing egg production.
2.1 Bacitracin	50–100			For chickens; as zinc bacitracin	Prevention of chronic respiratory disease (air-sac infection); blue comb (non-specific infectious enteritis).
3.1 Bacitracin	50–100			For turkeys; as zinc bacitracin	Prevention of infectious sinusitis, blue comb (mud fever).
4.1 Bacitracin	100			For chickens; as zinc bacitracin	Maintaining or increasing hatchability of eggs.
5.1 Bacitracin	100			do	During times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.
6.1 Bacitracin	100–500			do	Treatment of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).
7.1 Bacitracin	100–500			For chicks; in starter ration; as zinc bacitracin	Prevention of early mortality of chicks due to organisms susceptible to zinc bacitracin.
8.1 Bacitracin	100–500			For turkeys; as zinc bacitracin	Treatment of infectious sinusitis, blue comb (mud fever).

TABLE 2.—*Zinc bacitracin in complete swine feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Bacitracin	50–100			For swine; as zinc bacitracin	Aid in the prevention of bacterial swine enteritis
2.1 Bacitracin	100			do	Treatment of bacterial swine enteritis.

* * * * * * *

9. In § 121.237(d) by revising the table to read as follows:

§ 121.237 Nihydrazone.

* * * * * * *

(d) * * *

Nihydrazone in complete chicken feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Nihydrazone	100			For broilers; for replacement chickens not over 14 weeks of age; not for laying chickens.	Prevention of chronic respiratory disease (air-sac infection). In the presence of chronic respiratory disease (air-sac infection) to reduce mortality and severity of infection, to reduce the number of lesions, and assist in maintaining weight gains and feed efficiency. Prevention of pullorum disease; fowl typhoid; paratyphoid (salmonellosis); coccidiosis caused by *E. tenella*, *E. necatrix*, *E. maxima*, and *E. brunetti* and histomoniasis (blackhead).
a. Nihydrazone	100	Penicillin	2.4–50	As procaine penicillin	Growth promotion and feed efficiency.
b. Nihydrazone	100	Bacitracin	4–50	As bacitracin methylene disalicylate or zinc bacitracin.	Do.
c. Nihydrazone	100	Chlortetracycline	10–50	As chlortetracycline hydrochloride	Do.

* * * * * * *

10. In § 121.251(d) by revising table 1 to read as follows:

§ 121.251 Oxytetracycline.

* * * * * * *

(d) * * *

TABLE 1.—*Oxytetracycline in complete chicken and turkey feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Oxytetracycline	50			For chickens and turkeys; as the mono-alkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	During times of stress, for prevention of diseases named in this section caused by organisms susceptible to the named levels of the oxytetracycline salt.
2. Oxytetracycline	50–100			For chickens; as the mono-alkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	Prevention of blue comb (nonspecific infectious enteritis).
3. Oxytetracycline	50–100			For turkeys; as the mono-alkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	Prevention of hexamitiasis.
4. Oxytetracycline	50–100			For chicks (first two weeks of life); for poults (first four weeks of life); as the monoalkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	Prevention of early mortality of chicks and poults due to organisms susceptible to the oxytetracycline salt.
5. Oxytetracycline	100–200			For turkeys; as the mono-alkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	Control of infectious sinusitis; prevention of infectious synovitis.
6. Oxytetracycline	100–200			For chickens; as the mono-alkyl (C_8-C_{18}) trimethyl ammonium salt of oxytetracycline.	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks; prevention of fowl cholera.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
7. Oxytetracycline	100–200			For turkeys; as the monoalkyl (C_8–C_{18}) trimethyl ammonium salt of oxytetracycline.	Control of blue comb (nonspecific infectious enteritis, mud fever); treatment of hexamitiasis.
8. Oxytetracycline	100–200			For chickens; as the monoalkyl (C_8–C_{18}) trimethyl ammonium salt of oxytetracycline in low-calcium feed containing 0.18 to 0.55% dietary calcium; not to be fed continuously for more than 5 days; low calcium feeds may be fed for a total of three 5-day periods through the first 10 weeks of life with an interim period of 5 days between each low-calcium feeding. Not to be fed to laying chickens.	Treatment of blue comb (nonspecific infectious enteritis); prevention of infectious synovitis; control of complicated chronic respiratory disease (air-sac infection) by lowering mortality and severity of disease during outbreaks; reduction of lesions and mortality due to organisms susceptible to oxytetracycline in the presence of complicated chronic respiratory disease (air-sac infection).
9. Oxytetracycline	200			do	Prevention of avian infectious hepatitis; prevention and control of *E. tenella*, cause of cecal coccidiosis.
10. Oxytetracycline	200			For chickens; as the monoalkyl (C_8–C_{18} trimethyl ammonium salt of oxytetracycline.	Control of infectious synovitis.
11. Oxytetracycline	200			For turkeys; as the monoalkyl (C_8–C_{18}) trimethyl ammonium salt of oxytetracycline.	Do.
12. Oxytetracycline	200			For chickens; as the monoalkyl (C_8–C_{18}) trimethyl ammonium salt of oxytetracycline; in low-calcium feed containing 0.18 to 0.55% dietary calcium; for 2 weeks from outbreak of disease, 5 days of low calcium and the remaining period on normal calcium; not to be fed to laying chickens.	Control of fowl cholera during periods of outbreaks.
13. Oxytetracycline	200	Nequinate	18.16 (0.002%)	For broiler or fryer chickens only; as the monoalkyl (C_8–C_{18}) trimethyl ammonium salt of oxytetracycline as provided by code No. 030 in § 135.501(c) of this chapter.	As an aid in the prevention of coccidiosis caused by *Emeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti* and *E. mivati*. For control of complicated chronic respiratory disease (air-sac infections), infectious synovitis, and treatment of blue comb (non specific infectious enteritis).

* * * * * * *

11. In § 121.252(d) by revising tables 1 and 2 to read as follows:

§ 121.252 Bacitracin methylene disalicylate.

* * * * * * *

(d) * * *

TABLE 1.—*Bacitracin methylene disalicylate in complete chicken and turkey feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Bacitracin	10–50			For chickens; 50 gm per ton first 4 to 6 weeks of egg production; 10–50 gm per ton for remainder of egg-laying period; as bacitracin methylene disalicylate.	Maintaining or increasing egg production.
2.1 Bacitracin	50–100			For chickens; as bacitracin methylene disalicylate.	Prevention of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).
3.1 Bacitracin	50–100			For turkeys; as bacitracin methylene disalicylate.	Prevention of infectious sinusitis, blue comb (mud fever).
4.1 Bacitracin	100			For chickens; as bacitracin methylene disalicylate.	Maintaining or increasing hatchability of eggs.
5.1 Bacitracin	100			do	During times of stress, prevention of diseases named in this section caused by organisms susceptible to bacitracin.
6.1 Bacitracin	100			For chicks; in starter ration; as bacitracin methylene disalicylate.	Prevention of early mortality of chicks due to organisms susceptible to the bacitracin methylene disalicylate salt.
7.1 Bacitracin	100–200			For chickens; as bacitracin methylene disalicylate.	Treatment of chronic respiratory disease (airsac infection); blue comb (nonspecific infectious enteritis).
8.1 Bacitracin	100–200			For turkeys; as bacitracin methylene disalicylate.	Treatment of infectious sinusitis, blue comb (mud fever).
9. Bacitracin	10	Carbarsone (not U.S.P.)	227–340.5	As prescribed in § 121.310(b), item 3	§ 121.310(b), item 3.

TABLE 2.—*Bacitracin methylene disalicylate in complete swine feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Bacitracin	50–100			For swine; as bacitracin methylene disalicylate	Aid in the prevention of bacterial swine enteritis.
2.1 Bacitracin	100			do	Treatment of bacteria swine enteritis.

* * * * * * *

12. In § 121.253(c) by revising the table to read as follows:

§ 121.253 Arsanilic acid.

* * * * * * *

(c) * * *

Arsanilic acid in complete chicken and turkey feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Arsanilic acid	90 (0.01%)			For chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
1.2 Arsanilic acid	90 (0.01%)	Amprolium	113.5–227 (0.0125%–0.025%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; withdraw 5 days before slaughter; as sole source or organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; prevention of coccidiosis.
1.3 Arsanilic acid	90 (0.01%)	Amprolium + Ethopabate	113.5–227 (0.0125%–0.025%) 3.6 (0.0004%)	For broiler chickens; withdraw 5 days before slaughter.	Do.
1.4 Arsanilic acid	90 (0.01%)	Amprolium	36.3–113.5 (0.004%–0.0125%)	For replacement chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; as follows:	Growth promotion and feed efficiency; improving pigmentation; development of active immunity to coccidiosis.

Growing conditions	Amount of amprolium in feed for birds, by age groups: Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Grams per ton	*Grams per ton*	*Grams per ton*
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

1.5 Arsanilic acid	90 (0.01%)	Zoalene	113.5 (0.0125%)	For broiler chickens, withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; prevention and control of coccidiosis.
1.6 Arsanilic acid	90 (0.01%)	do	36.3–113.5 (0.004%–0.0125%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Growing conditions	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0085%)

1.7 Arsanilic acid	90 (0.01%)	Amprolium	72.6–113.5 (0.008%–0.0125%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; prevention of coccidiosis caused by *E. tenella* only.
1.8 Arsanilic acid	90 (0.01%)	Buquinolate	75 (0.00825%)	For broiler chickens; withdraw 5 days before slaughter; do not feed to laying hens; as sole source of organic arsenic.	As an aid in the prevention of coccidiosis caused by *E. tenella*, *E. maxima*, *E. necatrix* and *E. acervulina*; growth promotion and feed efficiency; improving pigmentation.
2.1 Arsanilic acid	90 (0.01%)			For turkeys; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
2.2 Arsanilic acid	90 (0.01%)	Amprolium	113.5–227 (0.0125%–0.025%)	do	Growth promotion and feed efficiency; improving pigmentation; prevention of coccidiosis.
2.3 Arsanilic acid	90 (0.01%)	Zoalene	113.5–170.3 (0.0125%–0.01875%)	For turkeys grown for meat purposes only; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; prevention and control of coccidiosis.

* * * * * * *

13. In § 121.256(d) by revising tables 1 and 2 to read as follows:

§ 121.256 Penicillin.

* * * * * * *

(d) * * *

TABLE 1.—*Penicillin in complete chicken and turkey feeds*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Penicillin	50–100			For chickens; as procaine penicillin	Prevention of chronic respiratory disease (air-sac infection); blue comb (nonspecific infectious enteritis).
2.1 Penicillin	50–100			For turkeys; as procaine penicillin	Prevention of infectious sinusitis, blue comb (mud fever).
3.1 Penicillin+streptomycin.	90–180			For chickens; 90–180 gm. of combination, containing 16.7 percent of penicillin; as procaine penicillin+streptomycin sulfate.	Treatment of chronic respiratory desease (air-sac infection), blue comb (nonspecific infectious enteritis).
4.1 Penicillin+streptomycin.	90–180			For turkeys; 90–180 gm. of combination containing 16.7 percent of penicillin; as procaine penicillin+streptomycin sulfate.	Treatment of infectious sinusitis, blue comb (mud fever), hexamitiasis.
5.1 Penicillin	100			For turkeys; as procaine penicillin	Treatment of infection-sinusitis, blue comb (mud fever).

TABLE 2.—*Penicillin in complete swine feed*

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Penicillin+streptomycin.	45–90			For swine; 45–90 gm. of combination, containing 16.7 percent of penicillin; as procaine penicillin+streptomycin sulfate.	Aid in the prevention of bacterial swine enteritis.
2. Penicillin+streptomycin.	90			For swine; 90 gm. of combination, containing 16.7 percent of penicillin; as procaine penicillin+streptomycin sulfate.	Treatment of bacterial swine enteritis.
3. Penicillin+streptomycin.	90–270			For swine; 90–270 gm. of combination containing 16.7 percent of penicillin; feed not more than 14 days; as procaine penicillin+streptomycin sulfate.	Do.

* * * * * * *

14. In § 121.262(c) by revising the table to read as follows:

§ 121.262 3-Nitro-4-hydroxyphenylarsonic acid.

* * * * * * *

(c) * * *

3-nitro-4-hydroxyphenylarsonic acid in complete chicken and turkey feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)			For chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation.
1.2 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Zoalene	113.5 (0.0125%)	For broiler chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
1.3 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	do	36.3–113.5 (0.004%–0.0125%)	For replacement chickens; in complete feed only; grower ration not to be fed to birds over 14 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic; as follows:	Development of active immunity to coccidiosis; growth promotion and feed efficiency; improving pigmentation.

Growing Conditions	Starter ration	Grower ration
	Grams per ton	*Grams per ton*
Severe exposure	113.5 (0.0125%)	75.4–113.5 (0.0083%–0.0125%)
Light to moderate exposure	75.4–113.5 (0.0083%–0.0125%)	36.3–75.4 (0.004%–0.0085%)

1.4 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Alkomide	227 (0.025%)	For broiler chickens only; withdraw 5 days before slaughter; as sole source of organic arsenic.	Aid in the prevention of coccidiosis caused by *E. tenella* and *E. necatrix;* growth promotion and feed efficiency; improving pigmentation.
1.5 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Amprolium	113.5–227 (0.012%–0.025%)	For broiler chickens; for replacement where immunity to coccidiosis is not desired; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention of coccidiosis; growth promotion and feed efficiency; improving pigmentation.
1.6 Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Amprolium + Ethopabate	113.5–227 (0.0125%–0.025%) 3.6 (0.0004%)	For broiler chickens; for replacement chickens where immunity to coccidiosis is not desired; withdraw 5 days before slaughter; as sole source of organic arsenic; not for laying hens.	Do.
1.7 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Amprolium	36.3–113.5 (0.004%–0.0125%)	For replacement chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; as follows:	Growth promotion and feed efficiency; improving pigmentation; development of active immunity to coccidiosis.

Growing conditions	Amount of amprolium in feed for birds by age groups		
	Up to 5 weeks of age	From 5 to 8 weeks of age	Over 8 weeks of age
	Grams per ton	*Grams per ton*	*Grams per ton*
Severe exposure to coccidiosis	113.5 (0.0125%)	72.6–113.5 (0.008%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Moderate exposure to coccidiosis	72.6–113.5 (0.008%–0.0125%)	54.5–113.5 (0.006%–0.0125%)	36.3–113.5 (0.004%–0.0125%)
Slight exposure to coccidiosis	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)	36.3–113.5 (0.004%–0.0125%)

1.8 3-Nitro-4-hydroxyphenylarsonic acid.	22.7–45.4 (0.0025%–0.005%)	Buquinolate	75 (0.00825%)	For broiler chickens; withdraw 5 days before slaughter; do *not feed to laying* chickens; as sole source of organic arsenic.	As an aid in the prevention of coccidiosis caused by *E. tenella, E. maxima, E. necatrix,* and *E. acervulina:* growth promotion and feed efficiency; improving pigmentation.
1.9 3-Nitro-4-hydroxyphenylarsonic acid.	45.4 (0.005%)	Clopidol	113.5 (0.0125%)	For broiler chickens; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*
1.10 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	do	113.5 (0.0125%)	For replacement chickens intended for use as caged layers; do not feed to chickens over 16 weeks of age; withdraw 5 days before slaughter; as sole source of organic arsenic.	Aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati;* growth promotion and feed efficiency; improving pigmentation.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.11 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	Decoquinate	27.2 (0.003%)	For broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. mivati, E. acervulina, E. maxima,* and *E. brunetti;* growth promotion and feed efficiency; improving pigmentation.
1.12 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	Monensin	110 (as monensic acid activity).	For broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*
1.13 3-Nitro-4-hydroxyphenyl-arsonic acid.	22.7 (0.0025%)	Sulfadimethoxine+ ormetoprim	113.5 (0.0125%) 68.1 (0.0075%)	For broiler chickens only; withdraw 5 days before slaughter; as sole source of organic arsenic.	As an aid in the prevention of coccidiosi scaused by all *Eimeria* species known to be pathogenic to chickens, namely, *E. tenella, E. mecateix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and bacterial infections due to *H. gallinarum* (infectious coryza), *E. coli* (coli-bacillosis); and *P. multocida* (fowl cholera), growth promotion and feed efficiency; improving pigmentation.
1.14 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	Amprolium + Ethopabate + Lincomycin	113.5 (0.0125%) 3.6 (0.0004%) 2-4	For floor-raised broiler chickens; not for laying chickens; as lincomycin hydrochloride monohydrate; withdraw 5 days before slaughter; as sole source of amprolium and organic arsenic.	For increase in rate of weight gain; improved feed efficiency and pigmentation; as an aid in the prevention of coccidiosis in floor-raised broiler chickens.
1.15 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	Nequinate	18.16 (0.002%)	For broiler or fryer chickens only; feed continuously as sole ration throughout the starting period; withdraw 5 days before slaughter; as sole source of organic arsenic.	An aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati* in broiler chickens; growth promotion and feed efficiency; for improving pigmentation.
1.16 3-Nitro-4-hydroxyphenyl-arsonic acid.	45.4 (0.005%)	Monensin sodium	110 (as monensic acid activity).	For broiler chickens; do not feed to laying chickens; feed continuously as the sole ration; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; as an aid in the prevention of coccidiosis caused by *E. necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.*
1.17 3-nitro-4-hydroxy-phenyl-arsonic acid.	22.7-34.0 (0.0025%-0.00375%)	Buquinolate	75-100 (0.00825%-0.011%)	For broiler or fryer chickens; feed continuously as the sole ration; withdraw 4 days before slaughter; as sole source of organic arsenic; from buquinolate provided by sponsor No. 067, see § 135.501(c) of this chapter.	An aid in the prevention of coccidiosis caused by, *E. tenella, E. maxima, E. necatrix, E. brunetti* and *E. acervulina;* growth promotion and feed efficiency; improving pigmentation.
1.18 3-Nitro-4-hydroxy-phenylarsonic acid.	45.4 (0.005%)	Amprolium + Ethopabate	113.5 (0.0125%) 36.3 (0.004%)	§ 121.210(c), Table 1, subitem b. under item 7.1	§ 121.210(c), Table 1, subitem b. under item 7.1.
1.19 3-Nitro-4-hydroxy-phenylarsonic acid.	34 (0.00375%)	Amprolium + Ethopabate Bacitracin methylene disalicylate.	113.5 (0.0125%) 36.3 (0.004%) 5-35	§ 121.210(c), table 1, item 9.1	§ 121.210(c), table 1, under item 9.1.
1.20 3-Nitro-4-hydroxy-phenylarsonic acid.	34 (0.00375%)	Amprolium + Ethopabate + Bacitracin methylene disalicylate.	113.5 (0.0125%) 36.3 (0.004%) 20-35	§ 121.210(c), table 1, item 10.1	§ 121.210(c), table 1, under item 10.1.
2.1 3-Nitro-4-hydroxyphenyl-arsonic acid.	22.7-45.4 (0.0025%-0.005%)			For turkeys; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigementation.
2.2 3-Nitro-4-hydroxy-phenylarsonic acid.	22.7-45.4 (0.0025%-0.005%)	Zoalene	113.5-170.3 (0.0125%-0.018%)	For turkeys grown for meat purposes only; withdraw 5 days before slaughter; as sole source of organic arsenic.	Growth promotion and feed efficiency; improving pigmentation; prevention and control of coccidiosis.
3.1 3-Nitro-4-hydroxy-phenyl arsonic acid.	11-45 (0.0012%-0.005%)	Decoquinate + Bacitracin	27.2 (0.003%) 12-50	For broiler chickens; do not feed to laying chickens; withdraw 5 days before slaughter; as sole source of organic arsenic; as zinc bacitracin as provided by code No. 009, § 135.501(c) of this chapter; as decoquinate as provided by code No. 001, § 135.501(c) of this chapter, as 3-nitro-4-hydroxyphenyl-arsonic acid as provided by code No. 031, § 135.501(c) of this chapter.	As an aid in the prevention of coccidiosis caused by *E. tenella, E. necatrix, E. acervulina, E. mivati, E. maxima,* and *E. brunetti;* and for increased rate of weight gain and improved feed efficiency.

§§ 121.263, 121.264 [Revoked]

15. By revoking §§ 121.263 3,5-*Dinitrobenzamide* and 121.264 *Sulfanitran (acetyl-(p-nitrophenyl)-sulfanilamide)* and reserving them for future use.

16. In § 121.292(d) by revising the table to read as follows:

§ 121.929 Erythromycin thiocyanate.

* * * * * * * * *

(d) * * *

Erythromycin in animal feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1.1 Erythromycin	92.5			For chickens; feed for 2 days before stress and 3 to 6 days after stress; withdraw 24 hours before slaughter.	As an aid in the prevention of chronic respiratory disease during periods of stress.
2.1 Erythromycin	92.5			For chickens; feed for 7 to 14 days; withdraw 24 hours before slaughter.	As an aid in the prevention of infectious coryza.
3.1 Erythromycin	92.5			For turkeys; feed for 2 days before stress and 3 to 6 days after stress.	As an aid in the prevention of chronic respiratory disease during periods of stress.
4.1 Erythromycin	185			For chickens; feed for 5 to 8 days; do not use in birds producing eggs for food purposes; withdraw 48 hours before slaughter.	As an aid in the prevention and reduction of lesions and in lowering severity of chronic respiratory disease.
5.1 Erythromycin	185			For turkeys; feed for 5 to 8 days; do not use in birds producing eggs for food purposes.	Do.
6.1 Erythromysin	10-70			For swine; feed from 10 to 70 grams per ton to starter pigs up to 35 pounds of body weight and 10 grams per ton to grower-finishing pigs.	For increase in rate of weight gain and improved feed efficiency in starter and grower-finishing pigs.
7.1 Erythromycin	18.5			For laying chickens	As an aid in increasing egg production.

17. In § 121.310(b) by revising the table to read as follows:

§ 121.310 Carbarsone not U.S.P.).

(b) * * *

Carbarsone in complete turkey feed

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
1. Carbarsone	227–340.5 (0.025%–0.0375%)			For turkeys; feed continuously beginning 2 weeks before blackhead is expected and continue as long as prevention is needed; withdraw 5 days before slaughter; as sole source of organic arsenic.	For use as an aid in the prevention of blackhead.
2. Carbarsone	227–340.5 (0.025%–0.0375%)	Zoalene	113.5–170.3 (0.0125%–0.01875%)	For turkeys grown for meat purposes only; feed continuously beginning 2 weeks before blackhead and coccidiosis are expected and continue as long as prevention of blackhead and prevention and control of coccidiosis are needed; withdraw 5 days before slaughter; as sole source of organic arsenic.	Prevention and control of coccidiosis; aid in the prevention of blackhead.

PART 135e—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§§ 135e.2, 135e.10, 135e.31, 135e.34, 135e.46, 135e.51 [Amended]

18. In § 135e.2 *Reserpine* by revoking subitems a, b, and c following item 2 in the table in paragraph (g).

19. In § 135e.10 *Tylosin* by revoking item 2 in the table in paragraph (f).

20. In § 135e.31 *Aklomide* by revoking items 2 and 3 and subitems a through d following item 4 in the table in paragraph (g).

21. In § 135e.34 *Buquinolate* by revoking subitems a through d following item 5 in the table in paragraph (f).

22. In § 135e.46 *Clopidol* by revoking subitems a and c following item 6 in the table in paragraph (e).

23. In § 135e.51 *Decoquinate* by revoking subitems a and b following item 2 in the table in paragraph (g).

§ 135e.1000 [Reserved]

24. By revoking § 135e.1000 *Combination antibiotic drugs in animal feeds no longer sanctioned* and reserving it for future use.

PART 135g—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

§ 135g.4 [Amended]

25. In § 135g.4 *Bacitracin* by deleting from the text the words "manganese bacitracin."

§ 135g.45 [Reserved]

26. By revoking § 135g.45 *3,5-Dinitrobenzamide* and reserving it for future use.

§ 135g.59 [Reserved]

27. By revoking § 135g.59 *Sulfanitran* and reserving it for future use.

PART 144—EXEMPTIONS FROM CERTIFICATION REQUIREMENTS FOR ANTIBIOTIC DRUGS FOR VETERINARY USE

28. By revising § 144.26 to read as follows:

§ 144.26 Animal feeds bearing or containing new animal drugs subject to the provisions of section 512(n) of the act.

Animal feeds that bear or contain penicillin, streptomycin in combination with penicillin, chlortetracycline, bacitracin, feed grade bacitracin, feed grade zinc bacitracin, and bacitracin methylene disalicylate, with or without added suitable nutritive ingredients are exempt from the certification requirements of section 512(n) of the act provided they are the subject of and in compliance with regulations for their use in Subpart C of Part 121 or Part 135e of this chapter, or paragraph (a) of this section.

(a) The drugs are used as follows:

Product	Species	Use levels	Indications for use
1. Nicarbazin	Chickens	0.01–0.02 percent	For use solely in the prevention of outbreaks of coccidiosis in poultry flocks.
Procaine penicillin	do	2.4–50 g/ton	
2. Nicarbazin	do	0.01–0.02 percent	Do.
Bacitracin methylene disalicylate.	do	4–50 g/ton.	
3. Nicarbazin	do	0.01–0.02 percent	For use as an aid in the prevention of coccidiosis in poultry flocks.
Bacitracin methylene disalicylate.	do	4–50 g/ton.	
3-Nitro-4-hydroxy-phenylarsonic acid.	do	0.0025–0.005 percent.	
4. Nicarbazin	do	0.01–0.02 percent	Do.
Procaine penicillin	do	2.4–50 g/ton.	
3-Nitro-4-hydroxy-phenylarsonic acid.	do	0.0025–0.005 percent.	
5. Procaine penicillin	Swine	1.5–7.5 g/ton	Increase rate of gain and improve feed efficiency in growing swine; aid in the prevention of bacterial swine enteritis.
Streptomycin	do	7.5–37.5 g/ton.	
Arsanilic acid	do	45–90 g/ton.	
6. Penicillin	Chickens and turkeys.	2.4–25 g/ton	For use solely as a treatment for complicated chronic respiratory disease (air-sac infection), infectious sinusitis, blue comb (nonspecific infectious enteritis, mud fever), and hexamitiasis in poultry; as an aid in maintaining or increasing egg production of chickens, hatchability of eggs, prevention of early mortality of chicks when due to organisms that are sensitive to streptomycin and penicillin; and for improving feed efficiency of chickens or turkeys.
Streptomycin	do	15–75 g/ton.	
7. Penicillin	do	5–25 g/ton	For use in the prevention or treatment of bacterial swine enteritis.
Streptomycin	do	15–75 g/ton.	
8. Furazolidone and	Chickens and turkeys.	0.011 percent	Growth promotion and feed efficiency. For prevention of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed for the first 2 weeks of the birds' life. For treatment of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for at least 2 weeks, except when paratyphoid is due to *S. typhimurium*. For reduction of condemnations due to chronic respiratory disease air-sac complex associated with vaccination stress, feed continuously beginning at least 1 week before vaccination. For prevention of infectious hepatitis when fed continuously during the danger period. For control of coccidiosis in chickens, caused by *E. tenella*, *E. necatrix*, or *E. acervulina* when fed for 5 to 7 days or longer. For prevention of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed continuously. For prevention of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed throughout the danger period. For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed for 5 to 10 days. NOTE.—Severe outbreaks may require twice the level specified (i.e., 0.022 percent).
Bacitracin methylene disalicylate or	do	4–50 g/ton.	
Procaine penicillin	do	2.4–50 g/ton.	
9. Furazolidone and	Chickens and turkeys	0.011–0.022 percent	Growth promotion and feed efficiency. Aid in maintenance of feed consumption and growth and reduction of mortality and morbidity due to stress; for the control of the following nonspecific conditions: chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to a filterable agent), nonspecific enteritis (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed 5 to 10 days. Follow with preventive level to prevent recurrence.
Bacitracin methylene disalicylate or	do	4–50 g/ton.	
Procaine penicillin.	do	2.4–50 g/ton.	

Product	Species	Use levels	Indications for use
10. Furazolidone and Bacitracin methylene disalicylate or	Chickens and turkeys.	0.22 percent	For treatment of paratyphoid due to *S. typhimurium* when fed for 2 weeks. For treatment of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed for 2 to 3 weeks (following diagnosis). For treatment of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed for 2 weeks or longer (following diagnosis). For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), mud fever and quail disease (ulcerative enteritis) when fed for 5 to 10 days. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary.
	do	4–50 g/ton.	
Procaine penicillin	do	2.4–50 g/ton.	

Interested persons may, on or before October 7, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74–17221 Filed 8–5–74;8:45 am]

[21 CFR Part 135]

ANTIBIOTIC, NITROFURAN, AND SULFONAMIDE DRUGS IN THE FEED OF ANIMALS

Notice of Proposed Rule Making

An order was published in the FEDERAL REGISTER of April 20, 1973 (38 FR 9811), and amended in the FEDERAL REGISTER of September 5, 1973 (38 FR 23942), regarding § 135.109 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals* (21 CFR 135.109). The regulation was promulgated and amended following publication of notices of proposed rule making in the FEDERAL REGISTER of February 1, 1972 (37 FR 2444), and April 20, 1973 (38 FR 9830).

The regulation provides that the Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses of antibiotic, nitrofuran, and sulfonamide drugs in animal feeds by no later than 2 years following the effective dates of the orders, unless data are submitted which resolve conclusively issues which have been raised concerning the safety of such products to man and animals and their effectiveness under specific criteria established by the Food and Drug Administration based on the guidelines included in the report of the FDA Task Force on Antibiotics in Animal Feeds. Of particular concern are those usages which provide for administration of antibacterial drugs over an extended period of time (approximately 14 days or longer).

Section 135.109 requires that all persons or firms previously marketing identical, related, or similar products not the subject of approved new animal drug applications, shall have submitted for each such product a new animal drug application (NADA) by July 19, 1973, or, in the case of nitrofuran drugs, by December 4, 1973, if marketing is to continue during the interim. Persons or firms wishing to support the continued approval of such antibiotic, nitrofuran, and sulfonamide drugs shall submit, under the provisions of section 512(1) of the act, the following:

1. By July 19, 1973, records and reports of completed, ongoing, or planned studies, including protocols, on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin, and the sulfonamides, and for all other antibiotic drugs, by October 17, 1973; and for nitrofuran drugs by March 4, 1974.

2. By April 20, 1974, data from completed studies on the tetracyclines, streptomycin, dihydrostreptomycin, penicillin and the sulfonamides assessing the effect of the subtherapeutic use of the drug in feed on the salmonella reservoir in the target animal as compared to that in nonmedicated controls. Failure to complete the salmonella studies for any of these drugs by that time will be grounds for proceeding to withdraw approval.

3. By April 20, 1975, data satisfying all other specified criteria for safety and effectiveness, including the effect on the salmonella reservoir, for any antibiotic or sulfonamide drugs and by September 5, 1975, for the nitrofuran drugs, approved for subtherapeutic use in animal feeds. Drug efficacy data shall be summitted for each individual or combination antibacterial drug product subject to § 135.109 and not reviewed by the NAS/NRC Veterinary Drug Efficacy Study Group.

4. Progress reports on studies underway every January 1 and July 1 until completion.

In response to § 135.109, the Commissioner has received satisfactory submissions from a number of producers of drug premixes as well as from several producers of intermediate premixes. Intermediate premixes are essentially drug premixes diluted to a lesser drug concentration. The production and distribution in interstate commerce of an intermediate premix which contains a new animal drug require an approved application pursuant to section 512(b) of the act. These applications fulfill the safety and efficacy data requirements through authorized reference to data contained in the approved NADA covering the drug premix from which the intermediate premix is manufactured. It is conservatively estimated that there are over 10,000 intermediate premixes produced in the United States. As promulgated, the provisions of § 135.109 could be interpreted to require submissions from all intermediate premix manufacturers regarding the products they produce.

The Commissioner has concluded that, to avoid unnecessary duplication, § 135.109 should be amended to provide that at this time producers of intermediate premixes need not submit an NADA and data required under this section for the interim marketing of any intermediate premix produced solely from a premix that is in compliance with this section, if the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where a specific premix has been approved by regulation in 21 CFR Part 135e as of the date specified in § 135.109(b)(1). Upon completion of the studies required by this section, a determination will be made regarding the need for applications for such products to provide for their continued use.

The Commissioner has also concluded that § 135.109 should be amended to list the manufacturers of antibacterial premixes who have satisfactorily responded to § 135.109 along with the corresponding premixes and combination drug products whose continued interim marketing and use will be permitted on the basis of their compliance with this section. Revocation of all other products subject to this section is proposed elsewhere in this issue of the FEDERAL REGISTER.

The claims provided below are on the basis of current use and may be subject to change based upon an evaluation of efficacy data by the National Academy of Sciences/National Research Council, Drug Efficacy Study Group or submitted in response to § 135.109.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351; (21 U.S.C. 360b, 371(a))) and under the authority delegated to the Commissioner (21 CFR 2.120), it is proposed that § 135.109 be amended by revising paragraph (a) and by adding a new paragraph (g) to read as follows:

§ 135.109 Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals.

(a) The Commissioner of Food and Drugs will propose to revoke currently approved subtherapeutic (increased rate of gain, disease prevention, etc.) uses in animal feed of antibiotic and sulfonamide drugs whether granted by approval of new animal drug applications, master files and/or antibiotic or food additive regulations, by no later than April 20, 1975, or the nitrofuran drugs by no later than September 5, 1975, unless data are submitted which resolve conclusively the issues concerning their safety to man and animals and their effectiveness under specific criteria established by the Food

and Drug Administration based on the guidelines included in the report of the FDA task force on the use of antibiotics in animal feeds. All persons or firms previously marketing identical, related, or similar products except the nitrofuran drugs not the subject of an approved new animal drug application must submit a new animal drug application by July 19, 1973, or by December 4, 1973, in the case of nitrofuran drugs, if marketing is to continue during the interim. New animal drug entities with antibacterial activity not previously marketed, now pending approval or submitted for approval prior to, on, or following the effective date of this publication, shall satisfy such criteria prior to approval.

* * * * *

(g) The submission of applications and data required by paragraphs (a) and (b) of this section is not required for the continued manufacture of any intermediate premix which is produced solely from a premix that is in compliance with the requirements of this section: *Provided*, That the intermediate premix contains no drug ingredient whose use in or on animal feed requires an approved application pursuant to section 512(m) of the act and/or where the premix is approved by regulation in Part 135e of this chapter.

(1) The following antibacterial drug premixes manufactured by the designated sponsors are eligible for interim marketing based on their compliance with the requirements of this section:

Drug sponsor	Drug premix	Species	Use levels	Indications for use
Commercial Solvents Corp.	Zinc bacitracin	Chickens, turkeys, and swine.	§ 121.233 (tables 1 and 2) of this chapter.	§ 121.233 (tables 1 and 2) of this chapter.
Do.	do.	do.	§ 121.225 of this chapter.	§ 121.225 of this chapter.
Do.	do.	Cattle.	do.	Do.
S. B. Penick & Co.	Bacitracin methylene disalicylate.	Chickens, turkeys, and swine.	§ 121.252 (tables 1 and 2) of this chapter.	§ 121.252 (tables 1 and 2) of this chapter.
Do.	do.	do.	§ 121.225 of this chapter.	§ 121.225 of this chapter.
Do.	do.	Cattle.	§ 121.252 (table 3) of this chapter.	§ 121.252 (table 3) of this chapter.
Elanco Products Co.	Hygromycin B.	Chickens and swine.	§ 121.213 (tables 1 and 2) of this chapter.	§ 121.213 (tables 1 and 2) of this chapter.
Do.	Tylosin.	Swine.	§ 135e.10 of this chapter.	§ 135e.10 of this chapter.
Abbott Laboratories.	Erythromycin.	Chickens, turkeys, and swine.	§ 121.292 of this chapter.	§ 121.292 of this chapter.
The Upjohn Co.	Lincomycin.	Chickens.	§ 135e.49 of this chapter.	§ 135e.49 of this chapter.
Pfizer, Inc.	Oleandomycin.	Chickens and swine.	§ 135e.45 of this chapter.	§ 135e.45 of this chapter.
Hoechst Pharmaceuticals.	Bambermycins.	Chickens.	§ 135e.65 of this chapter.	§ 135e.65 of this chapter.
American Cyanamid Co., Diamond-Shamrock Chemical Co., Hess and Clark, Rachelle Labs, Inc., and Vitamin Premixers of Omaha.	Chlortetracycline.	Chickens, turkeys, swine, and cattle.	§ 121.208 (tables 1, 2, and 6) of this chapter.	§ 121.208 (tables 1, 2, and 6) of this chapter.
Do.	do.	do.	§ 121.225 of this chapter.	§ 121.225 of this chapter.
Merck, Sharpe & Dohme Research Labs.	Procaine penicillin.	Chickens, turkeys, and swine.	§ 121.286 (tables 1 and 2) of this chapter.	§ 121.256 (tables 1 and 2) of this chapter.
Do.	do.	do.	§ 121.225 of this chapter.	§ 121.225 of this chapter.
E. R. Squibb & Sons, Inc.	do.	Pheasant and quail.	do.	Do.
Merck, Sharpe, & Dohme Research Labs.	Sulfaquinoxaline.	Chickens.	Continuously, 0.0125–.025 percent.	Aid in prevention of coccidosis due to *Eimeria Tenella, E. necatrix, E. acervulina, E. brunetti, E. maxima.*
Do.	do.	Turkeys.	Continuously, 0.0175 percent.	Aid in prevention of coccidosis due to *Eimeria meleagrides, E. meleagrimites* and *E. adenocides.*
Do.	do.	Rabbits.	Continuously, 0.025 percent.	Aid in prevention of coccidiosis due to *Eimeria stiedae, E. perforens.*
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline.	Chickens and turkeys.	§ 121.251 (table 1) of this chapter.	§ 121.251 (table 1) of this chapter.
Do.	do.	Swine (10–30 lb).	25–50 g/ton.	To increase rate of gain and improve feed efficiency.
Do.	do.	Chickens and turkeys.	7½–10 g/ton.	Do.
Do.	do.	Swine (30–200 lb).	50 g/ton.	As an aid in the prevention of bacterial enteritis, also known as scours, baby pig diarrhea, vibrio dysentery, bloody dysentery and salmonellosis (necro or necrotic enteritis).
Do.	do.	Calves.	25–75 mg/head per day or in complete feed at 50 g/ton.	To increase rate of gain and improve feed efficiency. As an aid in the prevention of bacterial diarrhea.
Do.	do.	Cattle.	75 mg/head daily.	As an aid in reducing incidence and severity of bloat. As an aid in reducing incidence and severity of liver abscesses (for cattle weighing over 400 lb).
Do.	do.	do.	0.1–0.5 mg/lb of bodyweight daily.	As an aid in the prevention of bacterial diarrhea.
Hoffman-La Roche, Inc.	Sulfadimethoxine and Ormetoprim.	Chickens and turkeys.	§ 135e.55 of this chapter.	§ 135e.55 of this chapter.
Pfizer, Inc.	Oxytetracycline and Neomycin.	Chickens, turkeys, swine, and calves.	As provided in par. (g)(2) of this section.	As provided in par. (g)(2) of this section.
American Cyanamid Co. and Rachelle Labs, Inc.	Chlortetracycline, Sulfamethazine, and Penicillin.	Swine.	do.	Do.
Diamond Shamrock Chemical Co.	Chlortetracycline, Sulfathiazole, and Penicillin.	do.	do.	Do.
Hess & Clark and Norwich Pharmacal Co.	Furazolidone.	Chickens and turkeys.	0.00063–0.0011 percent (7½–10 g/ton).	To stimulate growth and improve feed efficiency of chickens and turkeys when fed continuously.
Do.	do.	do.	0.0055 percent (50 g/ton).	For prevention of fowl typhoid, paratyphoid, and pullorum in chickens and turkeys when fed continuously in birds older than 2 weeks of age. For aid in prevention of coccidiosis in chickens caused by *E. tenella, E. necatrix,* or *E. acervulina* when fed continuously.
Do.	do.	do.	0.0055–0.011 percent (50–100 g/ton).	Aid in maintenance of feed consumption and growth and reduction of morbidity and mortality due to stress and the following nonspecific conditions: Chronic respiratory disease (airsac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed continuously prior to or throughout the danger period and during times of stress.
Do.	do.	do.	0.011 percent (100 g/ton).	For prevention of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for the first 2 weeks of the birds' life and followed continuously thereafter by one-half this level (i.e., 0.0055 percent). For treatment of fowl typhoid, paratyphoid and pullorum in chickens and turkeys when fed for at least 2 weeks except when paratyphoid is due to *S. typhimurium.*

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Do	do	do	do	For reduction of condemnations due to chronic respiratory disease air-sac complex associated with vaccination stress, feed continuously beginning at least 1 week before vaccination. For prevention of infectious hepatitis when fed continuously during the danger period. For control of coccidosis in chickens caused by *E. tenella*, *E. necatrix*, or *E. acervulina* when fed for 5-7 days or longer and followed by one-half this level (i.e., 0.0055 percent) for 2 weeks to aid in preventing recurrence.
Do	do	do	do	For prevention of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed continuously. For prevention of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed throughout the danger period. For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), nonspecific enteritis (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed for 5-10 days and followed with one-half this level (i.e., 0.0055 percent) to aid in preventing recurrence. NOTE.—Severe outbreaks may require twice the level specified (i.e., 0.022 percent).
Do	do	do	0.011-0.022 percent (100-200 g/ton).	Aid in maintenance of feed consumption and growth, and reduction of mortality and morbidity due to stress; for the control of the following nonspecific conditions: Chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to a filterable agent), (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed 5-10 days. Follow with preventive level to prevent recurrence.
Do	do	Chickens	0.022 percent (200 g/ton)	For treatment of paratyphoid due to *S. typhimurium* when fed for 2 weeks. For treatment of blackhead (histomoniasis, enterohepatitis) in chickens and turkeys when fed for 2-3 weeks (following diagnosis). For treatment of paracolon in chickens and turkeys and hexamitiasis in turkeys when fed for 2 weeks or longer (following diagnosis). For control of chronic respiratory disease (air-sac), infectious sinusitis, synovitis (arthritis due to filterable agent), non-specific enteritis (bluecomb, mud fever) and quail disease (ulcerative enteritis) when fed for 5-10 days and followed with one-fourth this level (i.e., 0.0055 percent) to aid in preventing recurrences. For treatment of infectious hepatitis in chickens when fed for 14 days and repeated as necessary.
Do	do	Swine	§ 121.255 of this chapter	§ 121.255 of this chapter.
Do	Nitrofurazone	Chickens	0.0055 percent (50 g/ton)	Aid in prevention of coccidiosis when fed continuously.
Do	do	Turkeys	do	As an aid in controlling losses due to secondary bacterial invasions concurrent with coccidosis outbreaks when fed continuously throughout the danger period.
Do	Nihydrazone	Chickens	§ 121.237 of this chapter	§ 121.237 of this chapter.

(2) The following drug combinations are permitted when prepared from the anitbacterial drug premixes listed in paragraph (g) (1) of this section:

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
American Cyanamid Co. and Rachelle Labs, Inc.	Chlortetracycline	Swine	100 g/ton	§ 135e.61 of this chapter.
Do	Sulfamethazine	do	do	Do.
Do	Penicillin	do	50 g/ton	Do.
Diamond Shamrock Chemical Co.	Chlortetracycline	do	100 g/ton	§ 135e.58 of this chapter.
Do	Sulfathiazole	do	do	Do.
Do	Penicillin	do	50 g/ton	Do.
American Cyanamid Co	Chlortetracycline and Sulfamethazine.	Cattle	§ 121.208 (table 6) of this chapter.	§ 121.208 (table 6) of this chapter.
Pfizer, Inc., and Vitamin Premixers of Omaha.	Oxytetracycline	Chickens	50 g/ton	Prevention of diseases from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35-140 g/ton	Do.
Do	Oxytetracycline	Chickens	50-100 g/ton	Prevention of early chick mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do	Neomycin base	Chickens (first 2 weeks)	35-140 g/ton	Do.
Do	Oxytetracycline	Chickens	50-100 g/ton	To extend period of high egg production, to improve feed efficiency, to improve egg production and feed efficiency in presence of disease and at times of stress: As an aid in maintaining and improving hatchability where birds are suffering stress from moving, vaccinations, culling, extreme temperature changes, and worming; to improve livability of progeny when losses are due to oxytetracycline-susceptible organisms, to improve egg shell quality, prevention of blue comb (mud fever or nonspecific enteritis). As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with blue comb (mud fever or nonspecific enteritis).
Do	Neomycin base	do	35-140 g/ton	Do.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
Do		Oxytetracycline	do	100–200 g/ton	Prevention of complicated chronic respiratory disease (air-sac infection) and control of complicated chronic respiratory disease by lowering mortality and severity during outbreaks. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	35–140 g/ton	Do.
Pfizer, Inc		Oxytetracycline	Turkeys	50 g/ton	As an aid in the prevention of disease from oxytetracycline-susceptible organisms during periods of stress. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	35–140 g/ton	Do.
Do		Oxytetracycline	do	50–100 g/ton	To extend period of high egg production, to improve egg production, to improve feed efficiency, to improve fertility, to improve egg production and feed efficiency in presence of disease and time of stress; as an aid in maintaining and improving hatchability where birds are suffering from stress, exposure, moving, vaccination, culling, extreme losses due to oxytetracycline-susceptible organisms, and to improve egg shell quality; prevention of hexamitiasis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	35–140 g/ton	Do.
Do		Oxytetracycline	do	50–100 g/ton	As an aid in the prevention of early poult mortality due to oxytetracycline-susceptible organisms. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	Turkeys (first 4 weeks)	35–140 g/ton	Do.
Do		Oxytetracycline	Turkeys	100–150 g/ton	As an aid in reducing mortality in birds which have suffered an attack of air-sacculitis (it is recommended, wherever possible, to feed from time of attack to marketing).
Do		Neomycin base	do	35–100 g/ton	Do.
Do		Oxytetracycline	do	100–150 g/ton	As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	35–100 g/ton	Do.
Do		Oxytetracycline	do	100–200 g/ton	Control of bluecomb (mud fever or nonspecific enteritis), infectious sinusitis and hexamitiasis, prevention of infectious synovitis. As an aid in the prevention of bacterial enteritis and in the control of neomycin-sensitive organisms associated with bluecomb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	35–140 g/ton	Do.
Do		Oxytetracycline	do	200 g/ton	Control of infectious synovitis. For the treatment of bacterial enteritis and blue comb (mud fever or nonspecific enteritis).
Do		Neomycin base	do	70–140 g/ton	Do.
Pfizer, Inc., and Vitamin Premixers of Omaha.		Oxytetracycline	Swine	50 g/ton	As an aid in the prevention of bacterial enteritis (scours), baby pig diarrhea (in baby pigs only), vibrionic dysentery, bloody dysentery and salmonellosis (necro or necrotic enteritis).
Do		Neomycin base	do	35–140 g/ton	Do.
Do		Oxytetracycline	do	50–150 g/ton	As an aid in the maintenance of weight gains and feed consumption in the presence of atrophic rhinitis. As an aid in the treatment of bacterial enteritis.
Do		Neomycin base	do	70–140 g/ton	Do.
Pfizer, Inc		Oxytetracycline	Calves	50 g/ton	As an aid in the prevention of bacterial enteritis (scours).
Do		Neomycin base	do	35–140 g/ton	Do.
Do		Oxytetracycline	do	100 g/ton	As an aid in the treatment of bacterial enteritis (scours).
Do		Neomycin base	do	70–140 g/ton	Do.
Do		Oxytetracycline	do	8–100 mg/gal reconstituted milk replacer.	As an aid in the prevention of bacterial diarrhea (scours).
Do		Neomycin base	do	100–200 mg/gal reconstituted milk replacer.	Do.
Do		Oxytetracycline	do	40–200 mg/gal reconstituted milk replacer.	Do.
Do		Neomycin base	do	200–400 mg/gal reconstituted milk replacer.	Do.
Elanco Products Co		Tylosin and sulfamethazine	Swine	§ 135e.36 of this chapter	§ 135e.36.
The Upjohn Co		Lincomycin, amprolium, and ethopabate.	Chickens	§§ 135e.49 and 121.210 of this chapter.	§§ 135e.49 and 121.210.
Do		Lincomycin and buquinolate.	do	§§ 135e.49 and 135e.34 of this chapter.	§§ 135e.49 and 135e.34.
Do		Lincomycin and clopidol	do	§§ 135e.49 and 135e.46 of this chapter.	§§ 135e.49 and 135e.46.
Do		Lincomycin and decoquinate.	do	§§ 135e.49 and 135e.51 of this chapter.	§§ 135e.49 and 135e.51.
Do		Lincomycin and zoalene	do	§§ 135e.49 and 121.207 of this chapter.	§§ 135e.49 and 121.207.
Do		Lincomycin, amprolium, ethopabate, and 3-nitro-4-hydroxyphenylarsonic acid.	do	§§ 135e.49, 121.210, and 121.262 of this chapter.	§§ 135e.49, 121.210, and 121.262.
Do		Lincomycin and monensin	do	§§ 135e.49 and 135e.50 of this chapter.	§§ 135e.49 and 135e.50.
Do		Lincomycin and robenidine hydrochloride.	do	§§ 135e.49 and 135e.66 of this chapter.	§§ 135e.49 and 135e.66.
Do		Lincomycin, monensin, and 3-nitro-4-hydroxyphenylarsonic acid.	do	§§ 135e.49, 135e.50, and 121.262 of this chapter.	§§ 135e.49, 135e.50, and 121.262.

Principal ingredient	Grams per ton	Combined with—	Grams per ton	Limitations	Indications for use
Merck, Sharpe & Dohme Research Labs.		Procaine penicillin	Chickens and turkeys	2.4–7.5 g/ton	§ 121.225(a)(3)(iv) of this chapter.
Do		Streptomycin	do	12.0–37.5 g/ton	Do.
Do		Procaine penicillin	Chickens	3.75–7.5 g/ton	Do.
Do		Streptomycin	do	18.75–37.5 g/ton	Do.
Do		Procaine penicillin	Swine	1.5–7.5 g/ton	§ 121.225(a)(3)(vii) of this chapter.
Do		Streptomycin	do	7.5–37.5 g/ton	Do.
Do		Procaine penicillin	do	7.5–15 g/ton	§ 121.256 (table 2) of this chapter.
Do		Streptomycin	do	37.5–75.0 g/ton	Do.
Do		Procaine penicillin	do	1.5–7.5 g/ton	§ 144.26 of this chapter.
Do		Streptomycin	do	7.5–37.5 g/ton	Do.
Do		Arsanilic acid	do	45–90 g/ton	Do.
Do		Nicarbazin	Chickens	0.01–0.02 percent	Do.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		Nicarbazin	do	0.01–0.02 percent	§ 144.26 of this chapter.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Nicarbazin	do	0.01–0.02 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4.50 g/ton	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025–0.005 percent	Do.
Do		Nicarbazin	do	0.01–0.02 percent	Do.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025–0.005 percent	Do.
Do		Amprolium	Chickens and turkeys	0.0125–0.025 percent	§ 121.210 of this chapter.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Amprolium	Chickens	0.0125–0.025 percent	Do.
Do		Ethopabate	do	0.0004 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Amprolium	do	0.0125–0.025 percent	§§ 121.210 and 121.262 of this chapter.
Do		Ethopabate	do	0.0004 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025–0.005 percent	Do.
Do		Amprolium	Chickens and turkeys	0.004–0.025	§ 121.210 of this chapter.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		Amprolium	Chickens	0.004–0.25 percent	§§ 121.210 and 121.262 of this chapter.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do		Amprolium	do	0.0125–0.0125 percent	§ 121.210 of this chapter.
Do		Ethopabate	do	0.0004 percent	Do.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		Amprolium	do	0.0125–0.025 percent	§§ 121.210 and 121.262 of this chapter.
Do		Ethopabate	do	0.0004 percent	Do.
Do		Procaine penicillin	do	2.4–50 g/ton	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.0025–0.005 percent	Do.
Pfizer, Inc		Penicillin	Chickens and turkeys	2.4–25 g/ton	§ 144.26 of this chapter.
Do		Streptomycin	do	15–75 g/ton	Do.
Do		Penicillin	Swine	5–25 g/ton	Do.
Do		Streptomycin	do	15–75 g/ton	Do.
Hoffmann-La Roche, Inc		Sulfadimethoxine	Chickens	§ 135e.55 of this chapter	§ 135e.55 of this chapter.
Do		Ormetoprim	do	do	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	do	Do.
Do		Sulfadimethoxine	Turkeys	§ 135e.55 and § 135e.56 of this chapter.	§ 135e.55 and § 135e.56 of this chapter.
Do		Ormetoprim	do	do	Do.
Do		Ipronidazole	do	do	Do.
Dow Chemical Co		Zoalene	Chickens	0.0125 percent	§ 121.207 of this chapter.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		Zinc bacitracin	do	4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do		Zinc bacitracin	do	4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		Penicillin	do	2.4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do		Penicillin	do	2.4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		Arsanilic acid	do	0.01 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4–50 g./ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		Arsanilic acid	do	0.01 percent	Do.
Do		Penicillin	do	2.4–50 g/ton	Do.
Do		Zoalene	do	0.004–0.0125 percent	Do.
Do		Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		Penicillin	do	2.4–50 g/ton	Do.
Do		Zoalene	do	0.0125 percent	Do.
Do		3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do		Penicillin	do	2.4–50 g/ton	Do.

Drug sponsor	Drug ingredient	Species	Use levels	Indications for use
Do	Zoalene	do	0.0125 percent	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do	Zoalene	do	0.0125 percent	Do.
Do	Arsanilic acid	do	0.01 percent	Do.
Do	Penicillin	do	2.4–50 g/ton	Do.
Do	Zoalene	do	0.004–0.0125 percent	Do.
Do	Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do	Zoalene	do	0.004–0.0125 percent	Do.
Do	3-Nitro-4-hydroxyphenylarsonic acid.	do	0.005 percent	Do.
Do	Bacitracin methylene disalicylate	do	4–50 g/ton	Do.
Norwich Pharmacal Co	Furazolidone	Swine	0.022 percent (200 g/ton)	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery growth promotion while on medication when fed in prestarters, starters and growing rations to baby pigs and growing swine for 2 weeks. As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis.
Do	Oxytetracycline	do	50–150 g/ton	Do.
Do	Furazolidone	do	0.11 percent (100 g/ton)	Prevention of bacterial enteritis (necrotic enteritis, necro) and vibrionic (bloody) dysentery growth promotion while on medication when fed in prestarters, starters and growing rations to baby pigs and growing swine for 5 weeks.
Do	Oxytetracycline	do	50–100 g/ton	Do.
Do	Arsanilic acid	do	0.005–0.01 percent	As an aid in the maintenance of weight gains and feed consumption in presence of atrophic rhinitis. Growth promotion and feed efficiency.
Do	Furazolidone	Chickens and turkeys	0.011–0.022 percent (100–200 g/ton).	§ 144.26 of this chapter.
Do	Bacitracin methylene disalicylate.	do	4–50 g/ton	Do.
Do	Zinc bacitracin	do	do	Do.
Do	Procaine penicillin	do	2.4–50 g/ton	Do.
Do	Nihydrazone	Chickens	0.11 percent (100 g/ton)	§ 121.237 of this chapter.
Do	Procaine penicillin	do	2.4–50 g/ton	Do.
Do	Nihydrazone	do	0.11 percent (100 g/ton)	Do.
Do	Chlortetracycline	do	10–50 g/ton	Do.
Do	Nihydrazone	do	0.11 percent (100 g/ton)	Do.
Do	Bacitracin methylene disalicylate	do	4–50 g/ton	Do.
Do	Zinc bacitracin	do	do	Do.

Interested persons may, on or before October 7, 1974, file with the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: July 19, 1974.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.74–17222 Filed 8–5–74;8:45 am]